NATIONAL MARROW DONOR PROGRAM®

Entrusted to operate the C.W. Bill Young Cell Transplantation Program,
including Be The Match Registry℠

February 09, 2010

Cdr. Elizabeth Montcalm-Smith
Office of Naval Research (ONR 342)
875 N. Randolph St.
Arlington, VA 22203-1995

Subject: **Quarterly Performance/Technical Report of the National Marrow Donor Program®**

Reference: Grant Award #N00014-08-1-1207 between the Office of Naval Research and the National Marrow Donor Program

Dear Cdr. Montcalm-Smith:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of October 1, 2009 to December 31, 2009.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention (612-362-3403 or at cabler@nmdp.org).

Sincerely,

Carla Abler-Erickson

Carla Abler-Erickson, MA
Sr. Contracts Representative

Enclosure: Quarterly Report with SF298

C: D. Ivery – ACO (ONR-Chicago), letter and enclosure
Dr. Robert J. Hartzman, CAPT, MC, USN (Ret): letter and enclosure
Jennifer Ng, PhD – C.W. Bill Young Marrow Donor Recruitment and Research Program, letter and enclosure
J. Rike - DTIC (Ste 0944): letter and enclosure
NRL (Code 5227): letter and enclosure
Dennis Confer, MD, Chief Medical Officer, NMDP, letter only
Michelle Setterholm, NMDP letter only

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14. ABSTRACT

1. Contingency Prepardness: Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.

2. Rapid Identification of Matched Donors : Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenetic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation: Create a platform that facilitates multicenter collaboration and data management.

15. SUBJECT TERMS
Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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NATIONAL MARROW DONOR PROGRAM®

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Grant Award N00014-08-1-1207

QUARTERLY
PERFORMANCE / TECHNICAL REPORT
FOR
OCTOBER 01, 2009 to DECEMBER 31, 2009
PERIOD 5

Office of Naval Research

And

The National Marrow Donor Program
3001 Broadway Street N.E.
Minneapolis, MN 55413
1-800-526-7809

QUARTER PROGRESS REPORT

Development of Medical Technology for Contingency Response to Marrow Toxic Agents

April 01, 2009 through June 30, 2009

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IIA. Contingency Preparedness – Objective 1: Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians	
IIA.1 Task 1: Secure Interest of Transplant Physicians	**Period 5 Activity:** • During 2009 a total of 330 RITN center staff successfully completed the Basic Radiation Training (BRT); since its' creation in 2006 – 2,006 RITN center staff have successfully completed BRT; this is a passing rate of 96.6%
IIA.1 Task 2: GCSF in Radiation Exposure	**Period 5 Activity:** • No activity this period
IIA.1 Task 3: Patient Assessment Guidelines and System Enhancements	**Period 5 Activity:** **Donor Management and Online Access** application efforts were focused on required features and enhancements for the Donor Portal Contingency project. This project allows us to electronically contact the donors via email. It also allows them to update their contact information and complete an online Health History Questionnaire (HHQ) from the Online Access platform. Information provided by the donor is securely transferred to the donor's record facilitating reporting, storage and review of this information in established donor management systems. During the last quarter, new versions of the Donor Management and Online Access applications were delivered to production. Key features included were: • Initiation of Online HHQ • Ability of the HHQ to be completed online by the donor based on an email trigger • Ability for donor to review and update key contact information online to auto populate the Donor Management record • Review and verification of Online HHQs • Void of electronic HHQs to preserve integrity of stored documentation • Reports that display original responses from donors that have completed an Online HHQ and the status of all HHQs

Deployment Strategy included:

- Conducting a **Pilot** for the Health History Questionnaire (Online HHQ)
  - Timeline was from 11/1 – 11/30
  - Included the NMDP Call Back Unit and 3 Donor Centers
  - User acceptance and overall metrics measurements indicate a very successful outcome
- Conducting a final **Rollout** of the Online HHQ application
  - Completed on 11/30
  - Included all Domestic NMDP Network Donor Centers, with the exception of the DoD and DKMS Americas
  - Overall feedback and processing times continue to be monitored

Project outcomes captured to date indicate:

- **Donors are responsive to online tools.** New Online Health History Questionnaire functionality resulted in:
  - 701 **"Completed"** HHQs
  - 194 "**In Process**" HHQs between 10/1/09 – 12/31/09.
- **Donors report a high level of satisfaction with online tools.**
  - Approximately 40% of donors have given feedback through the email survey process
  - 94% of donors were able to complete the health questionnaire online
  - Donors rated the following as 'excellent'
    - Easy to Understand = 94%
    - Convenient = 91%
    - Visual Appeal Appearance = 82%
- **Online tools introduce great efficiency to key donor screening functions.** Average time to process an HHQ was reduced from 27 to13.5 minutes resulting in a 50% **reduction** in processing time per Online HHQ.

Given the high acceptance rate for this functionality along with the gains to productivity of donors screened

	using this method, it is expected that NMDP will gain: • The capability to double the capacity to process an HHQ using the same number of staff resources. • The ability to scale for a contingency event requiring confirmation of the availability and suitability of a large number of donors. Other efforts for the Contingency Project in the past quarter of 2009 included the following in process items: • Detailed project and budget plan for Event Portal (Preliminary Search) Release – scheduled for late 1st Qtr 2010. • Initial review of the Event Portal Screen functionality with the business. • Identification of an Enterprise Architecture approach for the Import Process for Preliminary Search. • Project Management and Quality Assurance components which will be used to manage the next release.
IIA.1 Task 4: National Data Collection Model	**Period 5 Activity:** • No activity this period.
IIA. Contingency Preparedness – Objective 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.	
IIA.2 Task 1: Contingency Response Network	**Period 5 Activity:** • Coordinated extensions of FY09 RITN participation agreements for five centers that did not complete all tasks by the end of September • Received and processed all submitted tasks into the RITN tracking database • Fifty (50) of the 57 participating RITN centers completed all tasks: o Three (3) new centers added to RITN in FY09 agreed to participate but did not start their tasks for FY09 (Mayo, MN; Vanderbilt, TN; Mayo, AZ) o Two centers asked to be placed inactive for FY09 (St. Jude TC, TN; COH DC, CA) o One center shall no longer be tracked for task accomplishment (DOD DC) o The HLA Registry DC asked to be inactive so they were removed from all tracking databases pending their proactive pursuit to resume participation in RITN

	• Conducted three Monthly RITN Conference Calls for center contacts to discuss issues related to the completion of tasks at their centers with the intent of sharing best practices between centers. • Created and distributed three "Radiation In the News" radiation event summary reports for distribution to RITN center staff to keep them abreast of radiological related incidents occurring around the globe.
IIA.2 Task 2: Sibling Typing Standard Operating Procedures	**Period 5 Activity:** • No activity this period
IIA. Contingency Preparedness – Objective 3: NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.	
IIA.3 Task 1: I.S. Disaster Recovery	**Period 5 Activity:** There were no significant modifications or changes to the Disaster Recovery Systems or Plan during this period. Routine maintenance was performed.
IIA.3 Task 2: Critical Facility and Staff Related Functions	**Period 5 Activity:** • **Business Continuity Planning:** o Published the organization Business Continuity Plan through the document control system o Pandemic influenza preparedness accomplished: ▪ Created and distributed to all staff a Pandemic Influenza Policies Overview pamphlet to set staffs expectations of how the NMDP would respond if a severe pandemic impacted the organization ▪ Provided H1N1 influenza situation updates to Senior Leadership ▪ Established an Influenza Season Response Team to monitor the impact of seasonal and H1N1 influenza to organization operations ▪ Continued to support the execution of "NMDP Flu Fighter" training on reducing the spread of influenza in the workplace; 91% of NMDP staff have completed the training o Emergency communications drills accomplished:

	▪ We were able to reach over 92% of NMDP staff using the bulk telephone Emergency Notification System (ENS) ▪ 57% of RITN centers successfully tested the use of their satellite telephone ▪ Successfully tested the NMDP Headquarters public address system ▪ 87% of the NMDP's Network of centers (368 of 422 centers) responded to an emergency notification email within 24 hours o Initiated planning for the 2010 Business Continuity Exercise
IIB. Rapid Identification of Matched Donors – Objective 1: Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.	
IIB.1 Task 1: Increase Registry Diversity	**Period 5 Activity:** **Cord Blood Recruitment** • Research with OB/GYN physicians has now been completed and analyzed. The research was conducted with U.S. OB/GYN physicians in two groups: those currently affiliated with a NMDP Network cord blood bank and those who are not currently affiliated. The research assessed awareness of the option to donate to a public cord blood bank and gained an understanding of barriers and motivations to supporting public donation. Results will shape new educational strategy and tactics to increase OB/GYN support of public donation. **Adult Donor Registry:** • No activity this period.

IIB.1 Task 2: Evaluate HLA-DRB1 High Res typing	**Period 5 Activity:** • This Task is closed.
IIB.1 Task 3: Evaluate HLA-C Typing of Donors	**Period 5 Activity:** • This Task is closed.
IIB.1 Task 4: Evaluate Buccal Swabs	**Period 5 Activity:** • No activity this period.
IIB.1 Task 5: Enhancing HLA Data for Selected Donors	**Period 5 Activity:** This aim consists of registry-based typing projects, which have the potential to strategically identify and improve the HLA typing and availability of donors most likely to match searching patients from domestic TCs. All strategies being evaluated are extensions of the previous Back-up Donor and Optimal Donor typing projects. • Evaluation of HLA-AB only typed donors potentially matching patients with formal searches: Patient searches with active work-up requests were evaluated and searches identified for which there are relatively few 6/6 matched donors. In previous reporting periods, 691 donors were selected from the HLA-AB only typed pool and HLA typing upgraded to intermediate-high resolution HLA-A, B, C, DRB1. Prospective typing was completed in March 2009. Continued follow-up of these donors revealed the cumulative activation of 11 donors for CT requests on behalf of 10 different patients. This was followed by 2 workup requests and 2 stem cell donations. • In previous reporting periods we performed an additional 566 donor selections for prospective HLA typing using our Optimal Donor selection strategies. Continued follow-up of these donors for patient-directed activation events revealed the cumulative activation of 8 donors for CT requests on behalf of 6 different patients, within an average of 147 days of the availability of upgraded HLA typing results. To date, one donor has been activated for a subsequent workup request.

IIB.1 Task 6: Maintain a Quality Control Program	**Period 5 Activity:** • No activity this period.
IIB. Rapid Identification of Matched Donors – Objective 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.	
IIB.2 Task 1: Collection of Primary Data	**Period 5 Activity:** • Ran program to "validate and push" probe results making them available to systems using HapLogic. Probe data from donors in the registry prior to February 2007 had already been pushed and have been used for searches; with this quarter's effort probe data from 395,417 donors since 2007 (about 35%) are starting to be used in searches.
IIB.2 Task 2: Validation of Logic of Primary Data	**Period 5 Activity:** • This Task is closed.
IIB.2 Task 3: Reinterpretation of Primary Data	**Period 5 Activity:** • This Task is closed.
IIB.2 Task 4: Genotype Lists & Matching Algorithm	**Period 5 Activity:** • No activity this period.
IIB. Rapid Identification of Matched Donors – Objective 3: Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor.	
IIB.3 Task 1: Phase I of EM Haplotype Logic	**Period 5 Activity:** • Internal testing by Scientific Services continued on the first prototype for HapLogic Phase III. Feedback is being collected for prioritization and incorporation into the project plan.

IIB 3 Task 2: Enhancement of EM Algorithm	**Period 5 Activity:** • Haplotype frequencies for 21 US populations were completed in September 2009 and have since been used for the registry modeling (discussed in more detail in IIB3.3). • Two (2) abstracts were submitted to the European Federation of Immunogenetics (EFI) 2010 meeting detailing the haplotype frequency dataset and its application in showing population differentiation.
IIB. Task 3: Optimal Registry Size Analysis	**Period 5 Activity:** • New methods for registry modeling have been implemented that allow the generation of adult donor match rates at the allele-level for HLA-A, -B, -C & -DRB1. Methods for analyzing cord match rates, incorporating cell dose limitations have been combined with donor match models to develop a platform for comprehensive analysis of match rates in the context of specific product/stringency search strategies by ethnicity and under several models of registry growth, and adult donor availability.
IIB.3 Task 4: Target Under- Repre-sented Phenotypes	**Period 5 Activity:** • In order to increase potential matches for Vietnamese patients, Vietnamese population centers in the US were determined from census demographic data. Donors were identified with the patient's most probable rare haplotype, and were then overlaid on Vietnamese population centers according to their zip code to identify the most likely areas for recruiting new potential matched donors.
IIB.3 Task 5: Bioinformatics Web Site	**Period 5 Activity:** • This Task is closed.
IIB.3 Task 6: Consultants to Improve Algorithm	**Period 5 Activity:** • This Task is closed.
IIB.3 Task 7: Population Genetics	**Period 5 Activity:** • No activity this period.

IIB.3 Task 8: Haplotype Matching	**Period 5 Activity:** • No activity this period.
IIB.3 Task 9: Global Haplotype/Benchmark	**Period 5 Activity:** • No activity this period.
IIB. Rapid Identification of Matched Donors – Objective 4: Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.	
IIB.4 Task 1: Expand Network Communications	**Period 5 Activity:** Project scoping meetings and requirements gathering have begun to identify the scope of work and details necessary to implement the Business to Business Gateway and Business Services in 2010 to support : • HLA typing results from NMDP contract laboratories (incorporating HLA nomenclature changes) • Inventory integration from affiliated business entities (i.e. EMDIS) • The implementation of HLA Override as a business service intended to validate and audit HLA results received from contract laboratories. • The formalization of pathways through which data are transmitted to NMDP from affiliates. • The development of the underlying capabilities to support the Version 3 WHO nomenclature requirements.
IIB.4 Task 2: Central Contingency Management	**Period 5 Activity:** **Donor Testing** • Donor testing continued for the research project to validate the "actual" 8/8 HLA high resolution match rates for both CAU and AFA patients and supply valuable information regarding donor selection in the event of a contingency. Donors are being tested in rounds of priority for cost efficiency. During this period, an additional group of CAU and AFA patients were each added to the overall cohort to increase the statistical power and provide a more refined 8/8 high resolution match rate. Four rounds of donor testing were performed (N=932 loci total) and results compiled for the analysis. Additional testing rounds will continue next quarter to complete the analysis. A decision was also made to expand the study to include a cohort of API and HIS cases to allow for

	the estimation and validation of the 8/8 match rate for those groups. This will allow for the study to provide results for the 4 largest patient broad race groups who search through the NMDP. Work on these groups will begin next quarter. **Medical Education Series on AML and MDS to be Implemented** • Based on the success of our first online continuing medical education (CME) series with an online educational partner (Clinical Care Options), a second series will be implemented. The content for this program is based on the NMDP symposium, *Navigating the Therapeutic Pathways for AML and MDS*, held prior to the ASH 2009 Annual Meeting. The program is scheduled to go live in Period 6 and will remain live online for one year. The goal of the program is to improve the application of transplantation, particularly the timing of referral, for patients with Acute Myelogenous Leukemia (AML) and Myelodysplastic Syndrome (MDS)
IIB.4 Task 3: Benchmarking Analysis	**Period 5 Activity:** • This Task is closed.
IIB.4 Task 4: Expand Capabilities of Collection and Apheresis Centers	**Period 5 Activity:** • This Task is closed.
IIC. Immunogenetic Studies – Objective 1: HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found.	
IIC.1 Task 1: Donor Recipient Pair Project	**Period 5 Activity:** In 1994 a retrospective D/R Pair HLA typing project to characterize class I and class II alleles of donor/recipient paired samples from NMDP's Repository was initiated. The goals of this ongoing research project are to assay the impact of DNA-based HLA matching on unrelated donor transplant outcome, develop strategies for optimal HLA matching, evaluate the impact of matching at alternative HLA loci on transplant outcome and finally to promote the development of DNA-based high resolution HLA typing methodologies. • 98% of Sample Group (SG) 23 pairs, whose period of performance came to a close on August 31,

	2009 have been audited and are available for inclusion in research studies. • The project period for SG24 came to a close on December 31, 2009. Initial audit analysis began. • Sample Group 25 (400pairs) was initiated on December 31, 2009. The period of performance is from December 31, 2009 to April 30, 2010. Current HLA matching guidelines for unrelated HCT recommend avoidance of mismatches only within the Antigen Binding Domain (ABD). This recommendation is based on the hypothesis that amino acid differences outside the ABD are not immunogenic. The ABD allo-reactivity assessment project will give insight into the allowable percent tolerance of matching needed outside of the ABD. • Initiated investigation of the first class II non-ABD mismatch (DRB1*140101/1454) where both alleles have been seen in the same genotype. Specific queries of the Be The Match Registry allowed for selection of ninety-nine potential donors to be typed at high resolution. • Selection of potential study participants has continued.
IIC. Immunogenetic Studies – Objective 2: Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.	
IIC.2 Task 1: Analysis of non-HLA loci	**Period 5 Activity:** **IPR** The Immunobiology Project Results (IPR) database and its applications will allow for storage and analysis of all immunogenetic data collected on NMDP research samples. This database will replace the existing HLA donor/recipient pair's database and facilitate storage and analysis of data from other immunogenetic loci (KIR, microsatellites, single nucleotide polymorphisms, etc). • The Scientific Services and Bioinformatics departments continued to collaborate on the design and development of the IPR database application and tools. • Quality assurance progressed and corrections were made on the application that accepts, validates, and stores incoming HLA and KIR typing data via HML. • Quality assurance was performed on reports that support the business user's ability to track typing requests and their results.

- Quality assurance and corrections were done on an application which loads transplant center typings.
- Quality assurance was performed on an application that compares typings between the labs and the transplant centers.
- Development was completed and quality assurance was initiated on software tools that monitor and resolve typing discrepancies.
- Development was initiated on software tools that allow the business user to monitor, alter, and audit data.
- Development was completed and quality assurance was initiated on software that automates the processing flow of the data from loading to data analysis to comparison between the labs to auditing to selection for study.

Preparation for User Acceptance testing of all completed functionality was begun.

KIR

In 2005 a pilot study to perform high resolution KIR gene typing was launched. The primary objectives of the study were to move technology forward from the current practice of locus level typing to high resolution typing, disseminate information and protocols in an open source mechanism and develop reference lines for use in individual laboratories.

- Typing of 78 potential news alleles produced a total of 46 novel alleles. All sequences were submitted and names received for all loci except KIR*3DL3. A publication is in development to describe the new alleles.
- The final 11 discrepancies from the high resolution KIR gene typing project were resolved via a tie breaker laboratory.
- Preparation continued on the KIR Typing Project manuscript.
- To date 1500 pairs from the Donor/Recipient pair's project have been typed for presence/absence of 14 KIR loci (2DL1-5, 2DS1-5, 3DL1-3 and 3DS1) and another 400 pairs have been enrolled.
- Comparison analysis of the KIR presence/absence typing on samples from SG24 is ongoing.

	• A total of 60 reference cell lines were selected for expansion. 58 lines succeeded and are now available for public request and use.
IIC.2 Task 2: Related Pairs Research Repository	**Period 5 Activity:** • Related transplant research sample collection continued with a pilot project initiated at seven TCs in December 2007. By the end of the reporting period, six TCs had submitted 838 samples (377 donor/recipient pairs) to the Repository. Development continues on the Research Sample Repository Tools suite to facilitate management of samples. Several enhancements were tested and released to production. • The whole genome amplification (WGA) project demonstrated the effectiveness of WGA using frozen DNA samples in July 2008 and cord blood samples in March of 2009. WGA is a promising alternative to Epstein Barr virus-induced B-lymphoblastoid cell line (B-LCL) transformation to provide a renewable source of DNA for low volume samples in the Repository and is suitable for use on PBMC, granulocytes, whole blood, B-LCL, previously extracted DNA and non-degraded filter paper. In 2009, the Histocompatibility Advisory Group approved the transition from B-LCL to WGA. The procedure is particularly valuable for the expansion of cord blood research samples due to the minute input requirements and will ensure that these extremely low volume precious samples are available for multiple studies. A set of 500 cord blood samples will be processed using WGA and will be included in the Donor/Recipient Pair HLA typing project next quarter.
IIC.2 Task 3: CIBMTR Integration	**Period 5 Activity:** • Drafted a task statement of work document, which builds a plan to integrate immunobiology data across disparate data sources (such as IDM and Research Specimens). • Started working on this by integrating infusion data from both FormsNet and SIP into one table, as well as infuse source and HLA, match grades and research inventory into one table.

IID. Clinical Research in Transplantation – Objective 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.

IID.1 Task 1: Observational Research, Clinical Trials and NIH Transplant Center

Period 5 Activity:

Observational Research

- Staff continued work on various observational studies within the area of Immunobiology, GVHD and Graft Sources Working Committees. A total of seven manuscripts were submitted and one manuscript was published during this reporting period.
- A total of twenty studies (fourteen oral and six posters) from all nineteen Working Committees were presented at the ASH meetings in December 2009.

Prospective Studies; RCI BMT

- During this report period, follow up activities continued for donors participating in the PBSC vs. Marrow clinical trail. Staff continues to support this activity including monitoring.
- Adult Double Cord trial activity during this period included three patients being enrolled for a total of twenty-four patients accrued to this study, giving a 44% completion rate. Staff continues to coordinate and complete monthly PI and coordinator calls, manage data collection and monitor sites.
- Revlemid trial activity continued during this period. Sites continued to enroll patients onto this study using the EMMES developed data capture forms. Minor revisions to the data capture system have been identified and have or are currently being revised.

Cord Blood

- The challenge grant application to the NHLBI to support a study to investigate biomarkers associated with cord blood engraftment was not awarded. The study protocol was re-evaluated and revised to allow the study to proceed with ONR support.
    - The Duke and MD Anderson laboratory staff continued work on validating the assay methodologies to ensure consistent results were generated at both testing sites. The study will proceed upon statistical verification of the validation testing results.

- Work continued on the observational study of single versus double cord blood transplants in adults. Further analyses were requested and completed.
- NMDP staff organized and prepared materials for two cord blood workshops that were presented at the 2009 NMDP Council Meeting.
    - Cord Blood Transplants in Adults: A Growing Therapy: Session objectives were to review history of cord blood transplantation in adult patients, to discuss current practices in adult cord blood transplants, and to describe the role of cord blood in the future of adult stem cell transplantation.
    - Strategies for Improving Outcomes in Cord Blood Transplant: Research and Practice: Session objectives were to review historical outcome data for cord blood transplant, to discuss the limitations of cord blood transplants, and to discuss innovation techniques that focus on improving cord blood transplant.
- Work continued on the development of a white paper detailing recommendations/guidelines for the assessment of new assays (potency or other assays) relevant to cord blood banking and/or transplantation. The final draft of the paper will be completed for review at the June 2010 Cord Blood Committee meeting.
- NMDP staff prepared materials and provided an update on the research sub-Committee activities at the November Cord Committee Meeting.
    - The full committee recommended initiation of a study to validate the findings in a recent publication by Jon van Rood and the New York Blood Center on the impact of non-inherited maternal antigen matching in cord blood transplantation.
    - A survey was distributed to the network cord blood banks to determine the availability of maternal HLA typing data and/or samples for testing.
    - The IBWC will conduct the validation analysis in cooperation with the research sub-Committee and the CIBMTR Graft Sources Working Committee.

AGNIS Activity:

- Coordinated user acceptance testing for AGNIS 2.0 Publish and retrieve functionality with CIT staff for data included in the SCTOD. SCTOD user acceptance testing of this functionality is complete and verified.
- Supported StemSoft's use of AGNIS 2.0 retrieve functionality and assisted with data preparation for internal testing of BMTbase product. BMTbase will allow transplant centers to retrieve FormsNet 2 form data for local reporting.
- Completed plan for implementation of AGNIS 2.0 Publish and retrieve functionality. Functionality will be implemented in early January, will initially support retrieval of forms 2400, 2450, and 2900.
- Completed internal QA for AGNIS 2.0 form Submission for Forms 2400 (pre-TED) and 2450 (TED), functionality released to external development site for use by transplant centers.
- Completed development and internal QA for AGNIS 2.0 form Submission for Form 2004 (IDM), functionality released to external development site for use by transplant centers.
- Completed development and began internal QA for AGNIS 2.0 form Submission for form 2005 (HLA).
- Began development and preparation for QA of AGNIS Enhanced Staging Client, a tool to support transplant center submission and retrieval of forms through AGNIS.
- Met with Roswell Park Cancer Institute regarding use of AGNIS Enhanced Staging Client in a beta site capacity.
- Met with Karmanos Cancer Institute and Mayo clinic to assist them in initial AGNIS set up and data mapping. Attendance at AGNIS weekly meeting with transplant centers has increased from typically 4 centers and 1 vendor to 7 centers and 3 vendors indicating increased interest in AGNIS.
- Kicked off a project to collaborate with the European group for Blood and Marrow Transplantation on mapping some EBMT forms to CIBMTR/SCTOD forms.

	FormsNet Activity • Code Freeze and sponsor authorization for implementation of FormsNet v2.9.1 (Donor Forms and Functionality updates). Planned delivery is January 4, 2010. • Code Freeze and sponsor authorization for implementation of FormsNet v2.11 (Clinical Trials Forms and Functionality). Planned delivery is January 4, 2010. • Code Freeze and sponsor authorization for implementation of FormsNet v2.10 (26 Recipient Forms updates/modifications). Planned delivery is January 4, 2010.
IID.1 Task 2: Research with NMDP Donors	**Period 5 Activity:** • Staff continued support of a Donor Ethnicity study with Dr. Galen Switzer from the University of Pittsburgh. • Staff continued to collaborate on a COG KIR study. Activities include facilitating the collection of a donor blood sample and shipment to the study lab. To date, 32 patients have been enrolled and 119 donor samples requested. • Staff continued to work on identifying and streamlining the operational processes needed to implement the protocol for long-term donor follow-up.
IID.1 Task 3: Expand Immuno-biology Research	**Period 5 Activity:** The CIBMTR IBWC met monthly during the quarter to discuss progress on ongoing research studies • The scientific director attended the ASHI and ASH annual meetings. o The IBWC sponsored a booth at the annual ASHI meeting to promote the activities of the committee and the resources offered through the NMDP Research Repository. • One manuscript was published: o Eric Anderson, et al. *Limited role of MHC class I chain–related gene A (MICA) typing in assessing graft-versus-host disease risk after fully human leukocyte antigen–matched unrelated donor transplantation*. Published. Blood, November 2009, 114: 4753-4754. • Two manuscripts were accepted for publication:

- Stephen Spellman, et al. *The Detection of Donor-Directed, HLA-Specific Alloantibodies in Recipients of Unrelated Hematopoietic Cell Transplantation is Predictive of Graft Failure.* Accepted in Blood.
- David McDermott, et al. *Donor and Recipient Chemokine Receptor CCR5 Genotype is Associated with Survival after Bone Marrow Transplantation.* Accepted in Blood.

- One manuscripts was submitted for publication:
  - Peter Shaw, et al. *Outcomes of Pediatric Bone Marrow Transplantation for Leukemia and Myelodysplasia Using Matched Sibling, Mismatched Related or Matched Unrelated Donors.* Submitted to Blood
- One abstract was submitted and accepted for presentation at the 2010 Tandem BMT annual meeting:
  - Lujia Dong, et al. *Similar Outcomes in Adults and Children Undergoing Family HLA-mismatched/haploidentical Hematopoietic Cell Transplantation.* Accepted for poster presentation.

ACRONYM LIST

AABB	American Association of Blood Banks	IDM	Infectious Disease Markers
AFA	African American	IHWG	International Histocompatibility Working Group
AGNIS	A Growable Network Information System	IPR	Immunobiology Project Results
AML	Acute Myelogenous Leukemia	ICRHER	International Consortium for Research on Health Effects of Radiation
ABD	Antigen Binding Domain	IND	Investigational New Drug
API	Asian Pacific Islander	IS	Information Services
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	IT	Information Technology
ASBMT	American Society for Blood and Marrow Transplantation	IRB	Institutional Review Board
ASHI	American Society for Histocompatibility and Immunogenetics	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
B-LCLs	B-Lymphoblastoid Cell Lines	KIR	Killer Immunoglobulin-like Receptor
BARDA	Biomedical Advanced Research and Development Authority	MDS	Myelodysplastic Syndrome
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	MHC	Major Histocompatibility Complex
BRT	Basic Radiation Training	MICA	MHC Class I-Like Molecule, Chain A
C&A	Certification and Accreditation	MICB	MHC Class I-Like Molecule, Chain B
CAU	Caucasian	MDACC	MD Anderson Cancer Center
CBMTG	Canadian Blood and Marrow Transplant Group	MSKCC	Memorial Sloan-Kettering Cancer Center
CBB	Cord Blood Bank	MUD	Matched Unrelated Donor
CBC	Congressional Black Caucus	NCBM	National Conference of Black Mayors
CBS	Canadian Blood Service	NCI	National Cancer Institute
CBU	Cord Blood Unit	NEMO	N-locus Expectation-Maximization using Oligonucleotide typing data
CHTC	Certified Hematopoeitic Transplant Coordinator	NHLBI	National Heart Lung and Blood Institute
CIBMTR	Center for International Blood & Marrow Transplant Research	NIH	National Institutes of Health

CIT	CIBMTR Information Technology	NIMS	National Incident Management System
CLIA	Clinical Laboratory Improvement Amendment	NK	Natural Killer
CME	Continuing Medical Education	NMDP	National Marrow Donor Program
CMF	Community Matching Funds	NRP	National Response Plan
COG	Children's Oncology Group	NST	Non-myeloablative Allogeneic Stem Cell Transplantation
CREG	Cross Reactive Groups	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
CSS	Center Support Services	OIT	Office of Information Technology
CT	Confirmatory Testing	OMB	Office of Management and Budget
CTA	Clinical Trial Application	ONR	Office of Naval Research
DC	Donor Center	P2P	Peer-to-Peer
DIY	Do it yourself	PBMC	Peripheral Blood Mononuclear Cells
DKMS	Deutsche Knochenmarkspenderdatei	PBSC	Peripheral Blood Stem Cell
DMSO	Dimethylsulphoxide	PCR	Polymerase Chain Reaction
DoD	Department of Defense	PSA	Public Service Announcement
DNA	Deoxyribonucleic Acid	QC	Quality control
D/R	Donor/Recipient	RCC	Renal Cell Carcinoma
EBMT	European Group for Blood and Marrow Transplantation	RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
EM	Expectation Maximization	REAC/TS	Radiation Emergency Assistance Center/Training Site
EMDIS	European Marrow Donor Information System	RFP	Request for Proposal
ENS	Emergency Notification System	RFQ	Request for Quotation
ERSI	Environment Remote Sensing Institute	RG	Recruitment Group
FBI	Federal Bureau of Investigation	RITN	Radiation Injury Treatment Network
FDA	Food and Drug Administration	SBT	Sequence Based Typing
FDR	Fund Drive Request	SCTOD	Stem Cell Therapeutics Outcome Database
Fst	Fixation Index	SG	Sample Group
GETS	Government Emergency Telecommunications Service	SLW	STAR Link® Web
GCSF	Granulocyte-Colony Stimulating Factor (also	SSA	Search Strategy Advice

	known as filgrastim)		
GIS	Geographic Information System	SSO	Sequence Specific Oligonucleotides
GvHD	Graft vs Host Disease	SSP	Sequence Specific Primers
HCT	Hematopoietic Cell Transplantation	SSOP	Sequence Specific Oligonucleotide Probes
HHQ	Health History Questionnaire	STAR®	Search, Tracking and Registry
HHS	Health and Human Services	TC	Transplant Center
HIPAA	Health Insurance Portability and Accountability Act	TED	Transplant Essential Data
HIS	Hispanic	TNC	Total Nucleated Cell
HLA	Human Leukocyte Antigen	TSA	Transportation Security Agency
HML	Histoimmunogenetics Mark-up Language	UI	User Interface
HR	High Resolution	URD	Unrelated Donor
HRSA	Health Resources and Services Administration	WGA	Whole Genome Amplification
HSC	Hematopoietic Stem Cell	WMDA	World Marrow Donor Association
IBWC	Immunobiology Working Committee	WU	Work-up